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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,532	11/29/1999	SYLVIE LURIA	916/13	6388

7590

02/08/2005

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/449,532	LURIA, SYLVIE	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gerald G Leffers Jr., PhD	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-134 is/are pending in the application.
- 4a) Of the above claim(s) 1-23,49-91 and 114-134 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36,44-47 and 92-113 is/are rejected.
- 7) ☒ Claim(s) 24-35,37-43 and 48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 May 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>PTOL-206</u> .                         |

09/449,532

Applicant Copy


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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
09/449,532	11/29/1999	Sylvie Luria	916/13

EXAMINER	
ART UNIT	PAPER NUMBER
1636	02/07/2005

DATE MAILED:

The decision on the petition filed in the above entitled application is as follows:

☐ Delay in Prosecution Held Unavoidable (35 U.S.C. 133),  
Petition Granted \_\_\_\_\_

☐ Delayed Payment of Issue Fee Accepted (35 U.S.C. 151),  
Petition Granted \_\_\_\_\_

☒ Petition Granted Petition to Accept Color Drawings (Photographs filed 5/18/03 is granted)
☐ Petition Denied \_\_\_\_\_

☐ Petition Dismissed \_\_\_\_\_

 By direction of the Deputy  
Assistant Commissioner for Patents

*Remy Yucel*  
**REMY YUCEL, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

### **DETAILED ACTION**

The instant application was abandoned on 6/4/2001 for failure to file a response to the outstanding action of 10/25/2000. Applicant petitioned to have the application revived on 5/12/2003. The petition was subsequently granted and applicant notified in a letter mailed 5/28/2003. This action is in response to the newly amended claims submitted by applicant along with the petition filed on 5/12/2003.

#### ***Response to Amendment***

In the papers filed on 5/12/2003, several claims were amended (claims 24, 44, 47, 92, 103, 109 and 112). Claims 1-134 are pending in the instant application, with claims 1-23, 49-91 & 114-134 withdrawn from consideration as being directed to nonelected invention. Claims 24-48 & 92-113 are currently under consideration in the instant application.

Any rejection of record in the previous office action not addressed herein is withdrawn. This action is not final as there are new grounds of rejection made herein that were not necessitated by applicant's amendment of the claims in the response filed 5/12/2003.

#### ***Drawings***

The replacement sheets for drawings 1-8d were received on 5/12/2003. These drawings are accepted. Applicant's petition concerning color photographs/drawings is granted (see the attached document). The amendment of the specification at page 21, line 6, to include the required paragraph concerning the color figures has been entered into the file.

### ***Specification***

The Brief Description of the Drawings is objected to for Figures 1-4 in that there is no description in the Brief Description for various acronyms presented in the figures (e.g. LS, CRS, GFP, FPS, P, T7, etc.). While it is understood that such definitions are provided elsewhere in the specification (e.g. the working examples), such explanations for labels in the Figures would clarify that which is illustrated in Figures 1-4 and aid the skilled artisan in understanding the invention. It would be remedial to amend the specification at the Brief Description of the Drawings to spell out each of the acronyms presented in Figures 1-4.

### ***Abstract***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract submitted for the instant specification is ~240 words in length. In addition, the abstract should be rewritten to describe the elected invention in more particular detail.

### ***Claim Objections***

Claim 24 is objected to because of the following informalities: the phrase "...when compared to a predetermined level of said expression of said reporter molecule..." is somewhat

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confusing. Technically, there is no clear and positive prior antecedent basis for the words “*said* expression of said reporter molecule” in the newly added phrase “when compared to a predetermined level of said expression of said reporter molecule” (examiner’s emphasis added). The only other reference to a level of expression of the reporter molecule in the preceding body of the claims is the test level in the presence of the one of the plurality of polypeptides, which is then compared to the predetermined level of expression. The claim is not rejected under 112 2<sup>nd</sup> paragraph for being vague and indefinite because the skilled artisan can reasonably determine what are intended to be the metes and bounds of the claimed system. Yet, the claim is potentially confusing and it would be helpful to remove the term “said” from the newly added words “said expression” in the penultimate line of the claim. Appropriate correction is required.

Claims 44 and 109 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Each of these claims recites the limitation, “...includes a polynucleotide sequence selected from the group consisting of a polynucleotide sequence represented in a genome and a polynucleotide sequence not represented in a genome...”. It is unclear how a polynucleotide sequence could not fall within either of the two members of the recited Markush group. Either a sequence is represented in a genome (i.e. of an organism of some type somewhere), or it is not. It appears from reading the specification (e.g. page 30, top paragraph) that applicants may intend the cited phrase to refer to sequences that are obtained directly from the genome of an organism (e.g. by restriction digest of genomic DNAs) or by

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recombinant/synthetic means (e.g. PCR-based amplification of RNAs). If this interpretation is correct, then it would be remedial to amend claims 44 and 110 to include language to this effect.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47 and 112 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicant's amendment of the claims in the response filed on 5/12/2003. This is a NEW MATTER rejection.**

Claims 47 and 112 have been amended to recite, "at least a 5 amino acid portion of a characterized polypeptide." The response filed 5/12/2003 does not point to the specification for support of the particular language inserted by the amendment, nor can the examiner find such literal support (e.g. a subgenus encompassing any polypeptide of greater than 5 amino acids in length). Therefore, the cited limitation from these claims is impermissible New Matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 36, 44-46 & 92-113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36 and 101 are vague and indefinite in that each recites a limitation whereby the cis regulatory sequence element that mediates expression of the first coding region on the first expression construct (i.e. encoding a transactivator) is a “translational regulatory sequence”. **This is a new rejection.** This limitation is unclear due to the fact that claims 24 and 92, upon which claims 36 and 101 are respectively dependent, recite that the first coding region is under the “transcriptional control” of the cis acting regulatory sequence element. It is unclear how the cis acting regulatory sequence element can be *both* a transcriptional and translational regulator of the first coding sequence since no such element is described in the instant specification. It would be remedial to amend the rejected claims by deleting the term “translational regulatory sequence” from the recited Markush group in each claim.

Claims 44 and 109 are vague and indefinite in that the metes and bounds of the phrase “...a polynucleotide sequence represented in a genome and a polynucleotide sequence not represented in a genome...” are unclear. **This is a new rejection.** The specification does not explain the concept of a sequence that is “represented in a genome”. For example, is the skilled artisan required to know whether the particular sequence present in the second expression construct is present or not in any particular genome for any particular organism out there in the world, whether or not that the sequence for that particular organism is known? If so, this amounts to a practical impossibility. It appears from reading the specification (e.g. page 30, top paragraph) that applicants may intend the cited phrase to refer to sequences that are obtained



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directly from the genome of an organism (e.g. by restriction digest of genomic DNAs) or by recombinant/synthetic means (e.g. PCR-based amplification of RNAs). If this interpretation is correct, then it would be remedial to amend claims 44 and 110 to include language to this effect.

Claim 92 is vague and indefinite in that there is no clear and positive prior antecedent basis for the newly added words "said cells in which said level of expression of said reporter molecule is within said predetermined range." No such cells have been mentioned in the claim up to that point. **This is a new rejection necessitated by applicant's amendment of the claims in the response filed on 5/12/2003.**

### *Conclusion*

Claims 36, 44-47 & 92-113 are rejected for reasons indicated above. Claims 24-35, 37-43 & 48 are objected to for reasons indicated above. All of the pending claims appear to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl

  
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